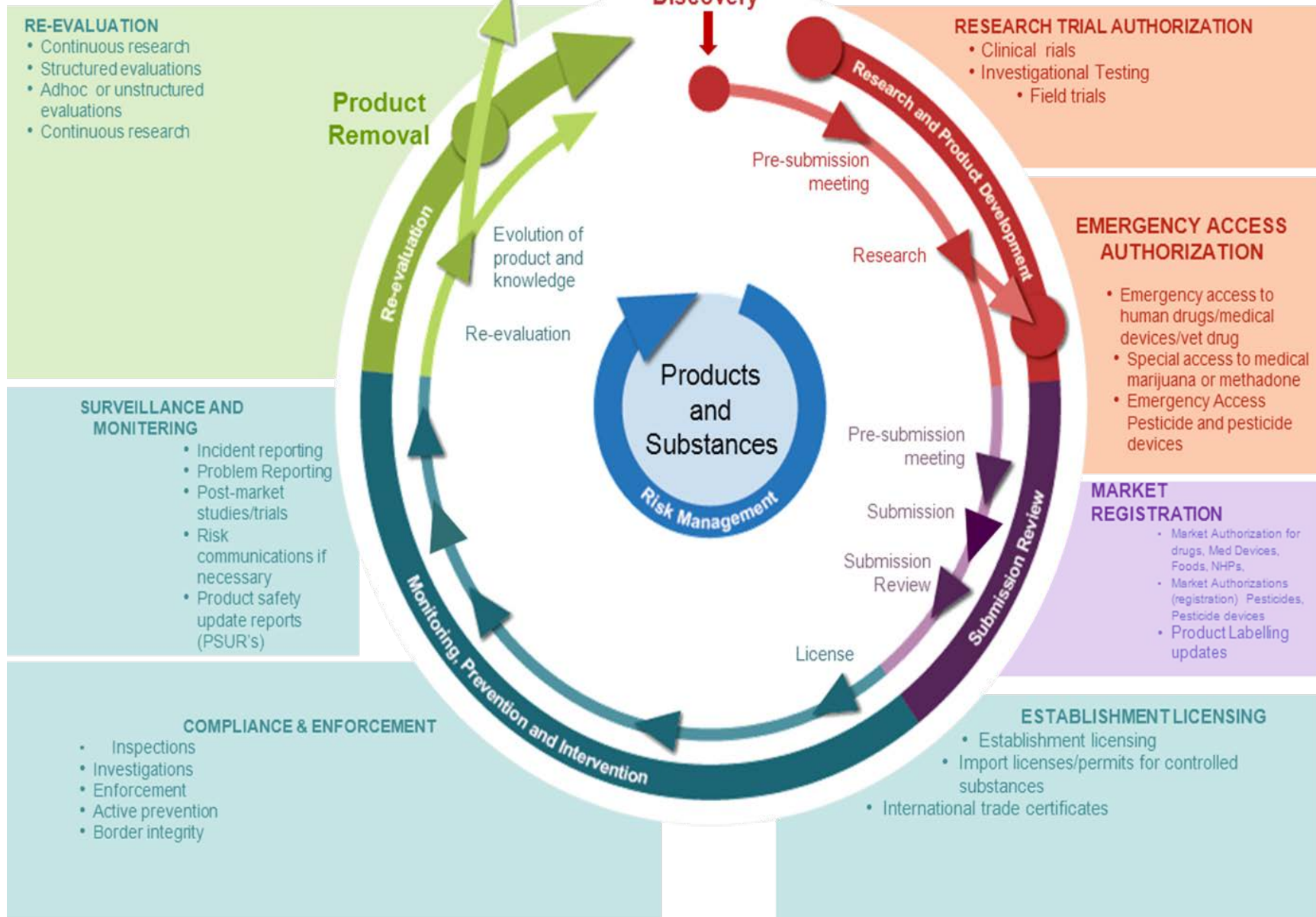


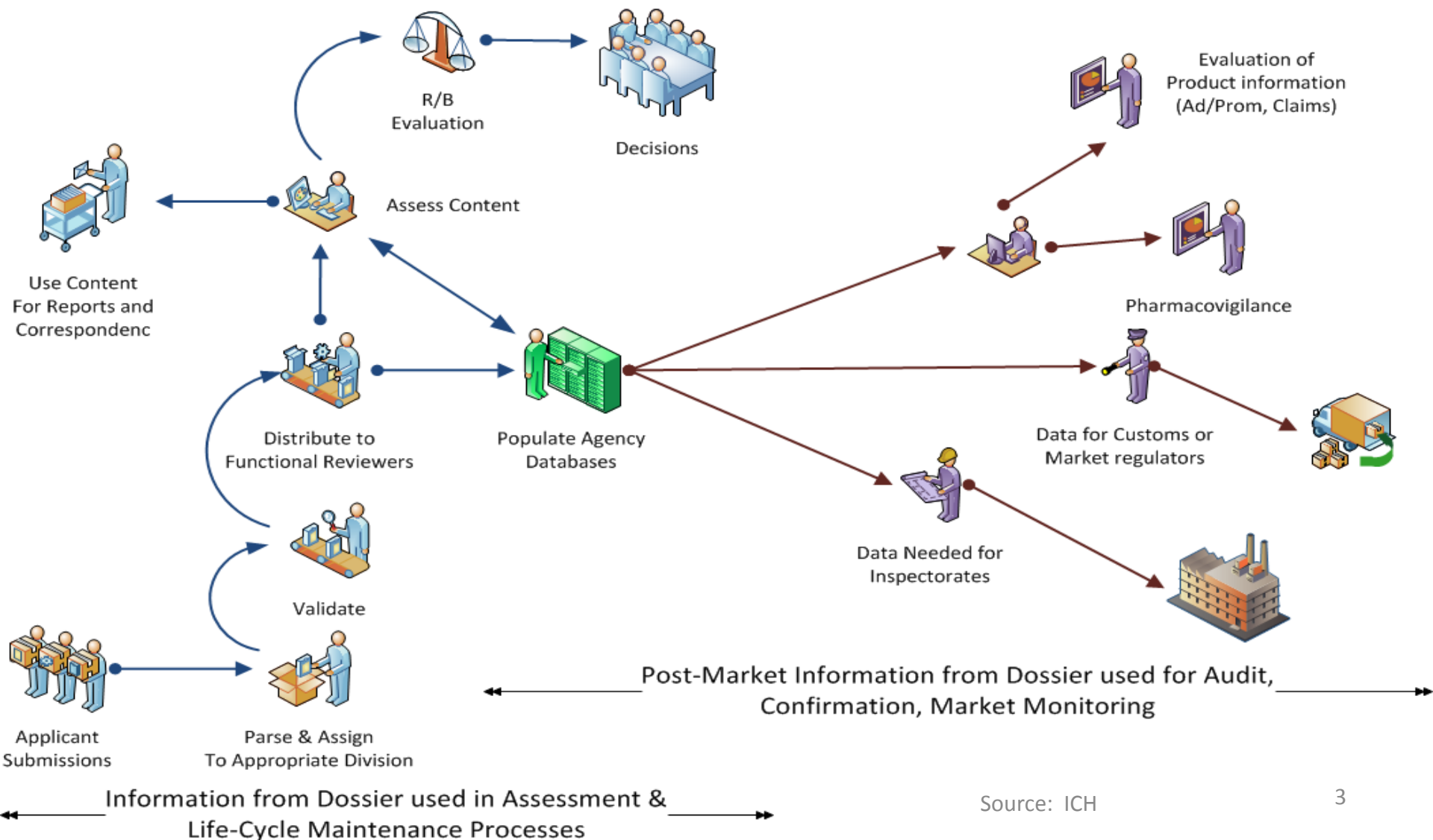


# Global Identification of Medicinal Products (IDMP):

Vada A. Perkins, CAPT, USPHS  
Senior Advisor for Regulatory Science  
ISO Identification of Medicinal Products  
(IDMP) Topic Lead  
U.S. Food and Drug Administration



# Regulatory Data Flow





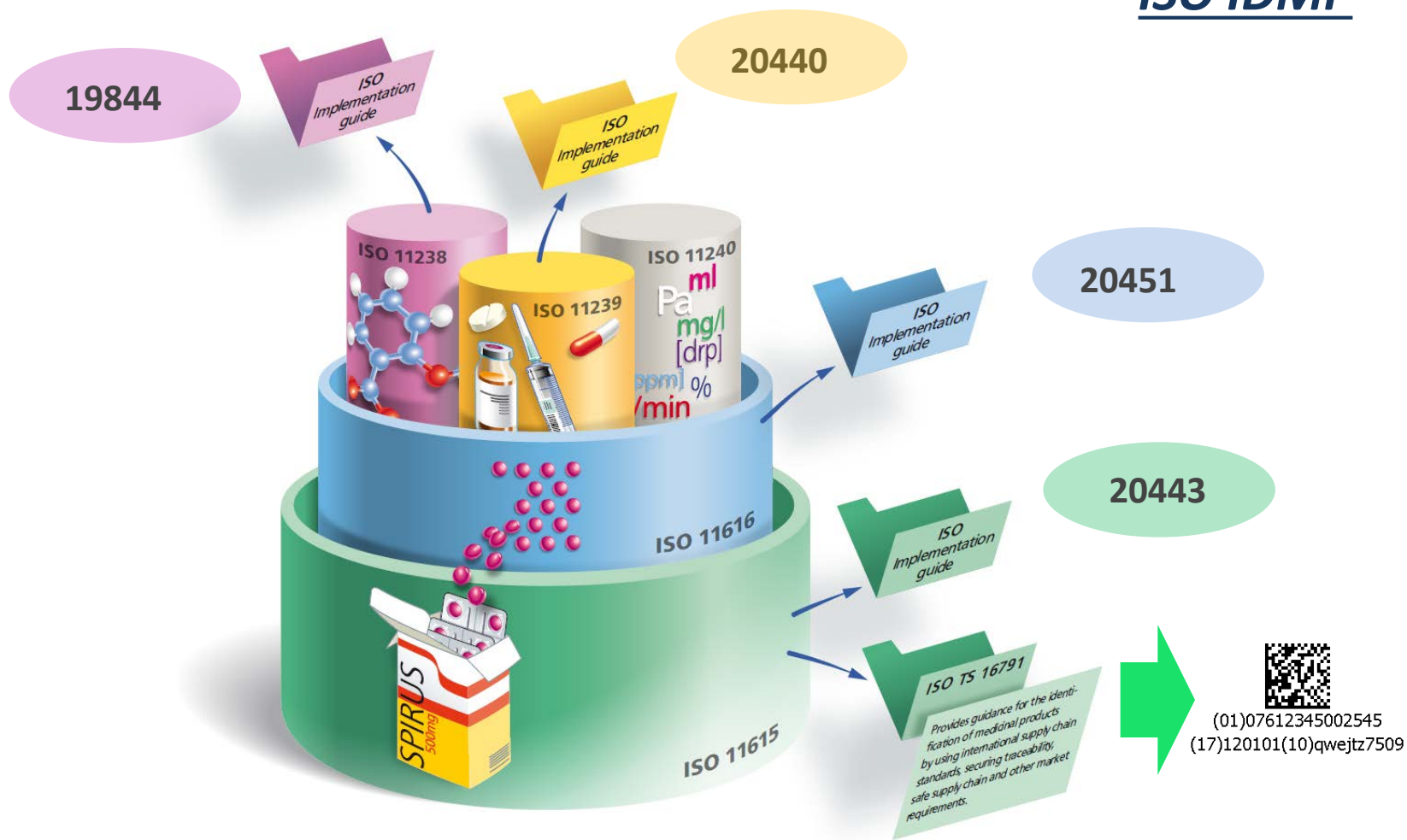
**U.S. Food and Drug Administration**  
Protecting and Promoting Public Health

[www.fda.gov](http://www.fda.gov)



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## ISO IDMP





**U.S. Food and Drug Administration**  
Protecting and Promoting Public Health

[www.fda.gov](http://www.fda.gov)





Source: <https://ashambaugh.wordpress.com/2015/01/29/amazons-organized-chaos/>

# Style Sheet View/Source Code (XML)

## CONTRAINDICATIONS

Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.

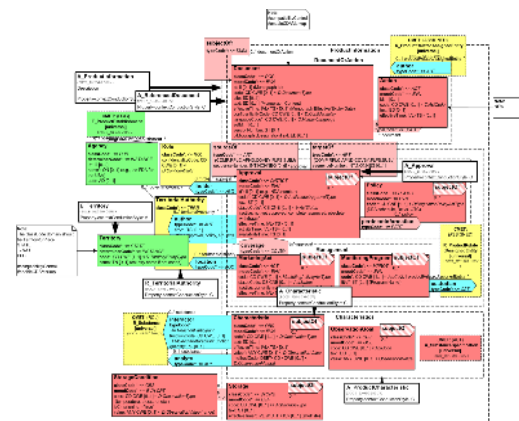
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<component>
<section ID="_7CF4D228-65A6-6223-5A96-ECB4DBD620FC">
<id root="3A7D815A-A2B9-0389-5D92-4836E709B0FE" />
<code code="34070-3" codeSystem="2.16.840.1.113883.6.1" displayName="CONTRAINDICATIONS SECTION" />
<title mediaType="text/x-hl7-title+xml">CONTRAINDICATIONS</title>
<text><paragraph>Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from
any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.</paragraph></text>
<effectiveTime value="20070813" />
</section>
```

# Incompatibility



## Standard e-Message for Data Exchange: Common Product Model (CPM)

- ▶ The Health Level Seven (HL7) Common Product Model (CPM) provides:



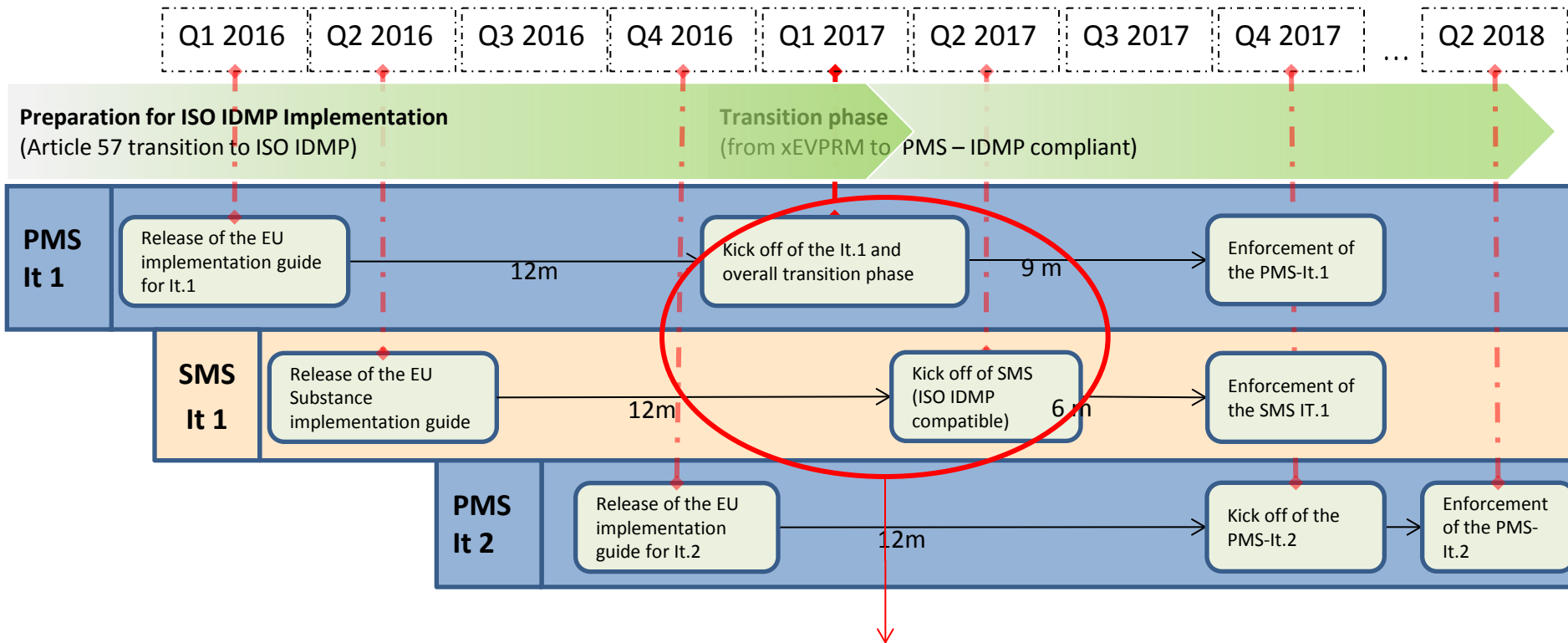
- ✓ **Overarching information model**
- ✓ **Reusable Common Message Element Types (CMETs)**
- ✓ **Consistent data types and conformance rules**
- ✓ **Vocabulary domains**
- ✓ **Schemas for data exchange**



# ISO IDMP Project Deliverables

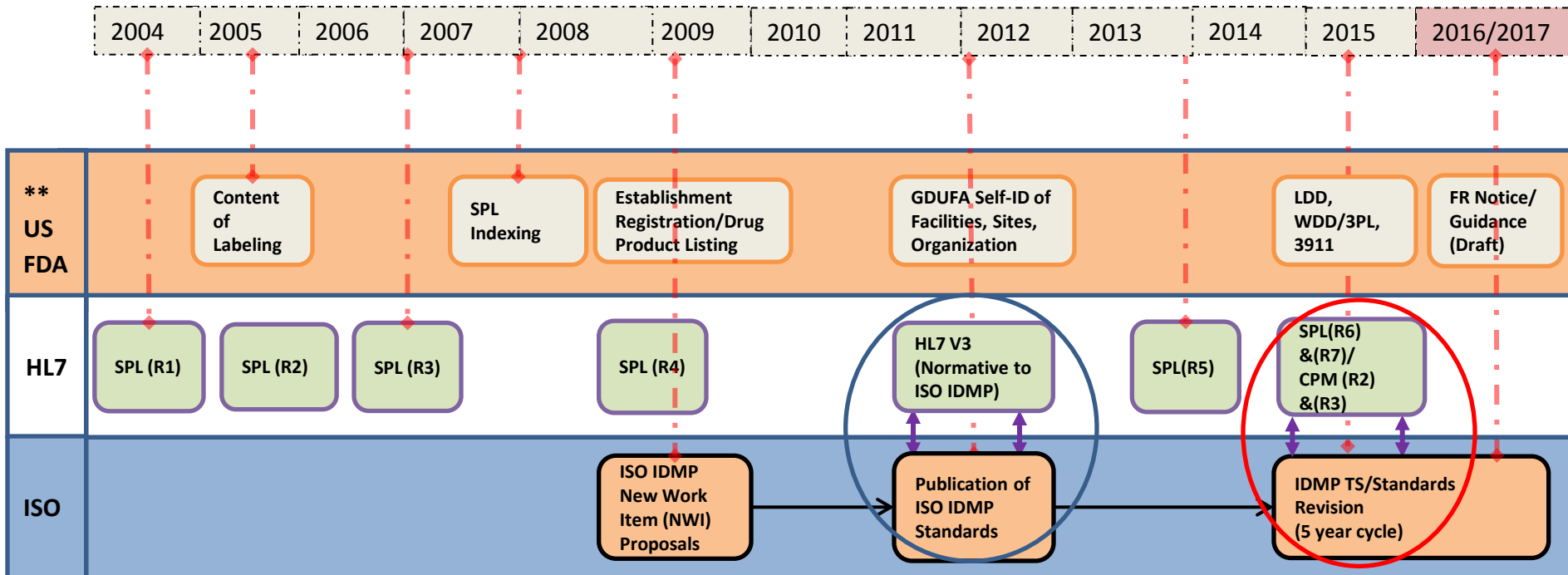
Document Name	Timelines			
	May 2016 ISO Meeting	Ballot, comment resolution or publication preparation	Nov 2016 ISO Meeting	Ballot, comment resolution or publication preparation
ISO Standard 11238 - Review	Decision to start DTS Ballot	DTS ballot ongoing	Decision to go for publication	<b>Publication</b>
ISO Standard 11615 - Review	Decision to start DTS Ballot	DTS ballot ongoing	Decision to go for publication	<b>Publication</b>
ISO Standard 11616 - Review	Decision to start DTS Ballot	DTS ballot ongoing	Decision to go for publication	<b>Publication</b>
ISO DTS 20443	Decision to publish	<b>Publication</b>		
ISO DTS 20451	Decision to publish	<b>Publication</b>		
ISO DTS 19844 V1: (chemical, proteins and nucleic acid)	<b>Published</b>			
ISO DTS 19844 V2: (blood, herbal, homeopathic, polymers )	Decision to publish	<b>Publication</b>		
ISO DTS 19844 V3: (vaccines, allergens, advanced therapy, cell and gene therapies)	Decision to go for a DTS ballot	Ballot and comment resolution	Decision to publish	<b>Publication</b>

# European Medicines Agency (EMA) S&P original plan



Paper to Electronic Submission (HL7 CPM/SPL, eCTD)

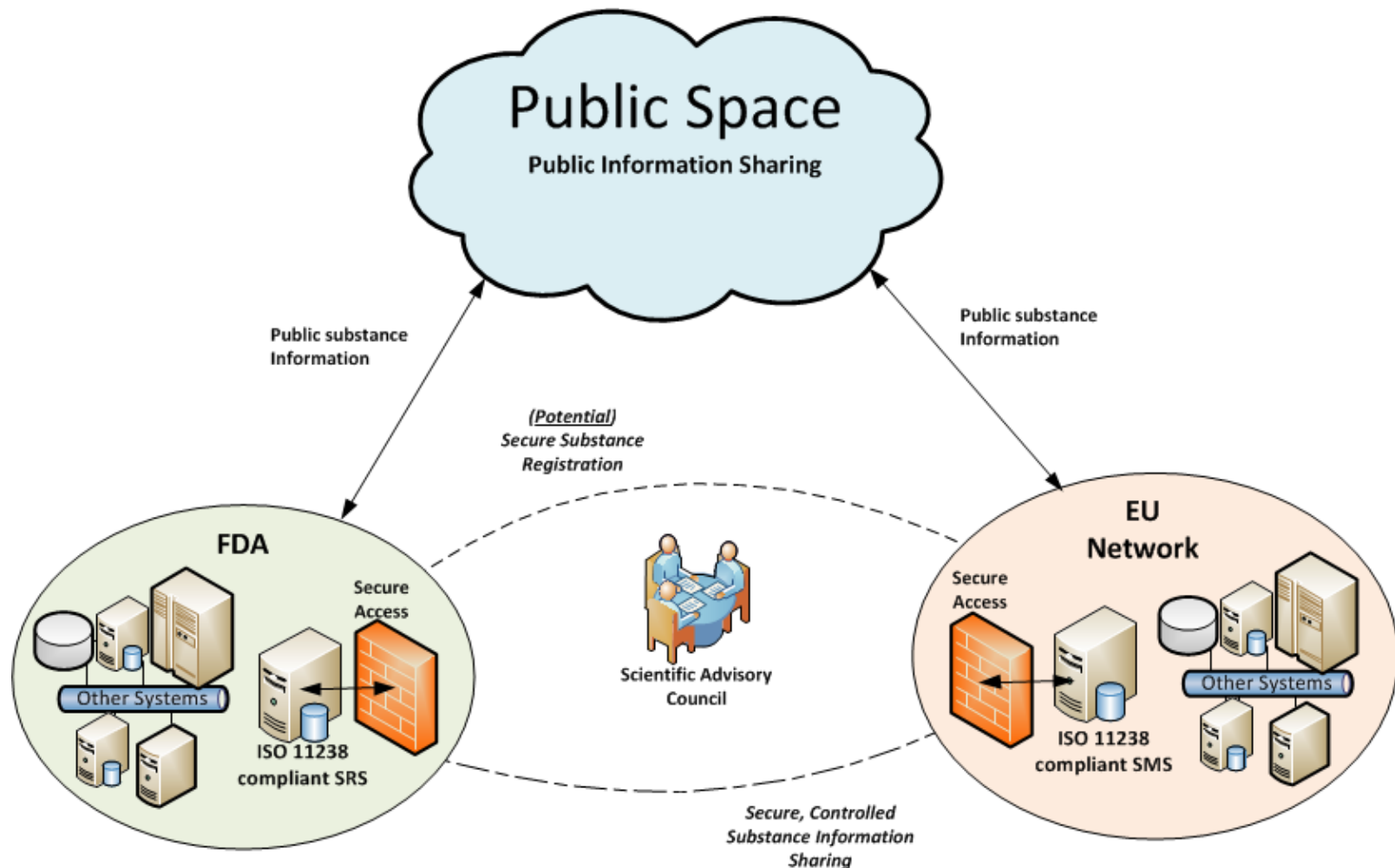
Transition phase to ISO IDMP Publication



# US FDA IDMP Roadmap

**\*\*US FDA SPL Implementation Guide (technical specification) updated with corresponding Guidance for Industry (incorporated by reference)**  
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm2005542.htm>

# Example: FDA/EU-EMA Data Exchange Model



# Thank You



Lost time is never found again.

(Benjamin Franklin)

[izquotes.com](http://izquotes.com)